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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KENNETH K. SOKOLL

Appeal 2009-006283[1]
Application 10/076,674
Technology Center 1600

Decided: January 4, 2010

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to an immunostimulatory complex between a peptide and an oligonucleotide. The Examiner rejected the claims as obvious.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] United Biomedical, Inc. is the real party in interest.

STATEMENT OF THE CASE

Claims 1, 4-9, 12, 13, 18, and 19 stand rejected and appealed (Ans. 2). Claim 1, the only independent claim, is representative and reads as follows:

> 1. A stabilized immunostimulatory microparticulate complex comprising a cationic peptide immunogen wherein the peptide immunogen comprises a target B cell antigen or a CTL epitope and a T helper cell epitope and an anionic CpG oligonucleotide wherein the cationic peptide immunogen has a net positive charge at a pH in the range of 5.0 to 8.0 calculated by assigning a +1 charge for each lysine (K), arginine (R) or histidine (H), a -1 charge for each aspartic acid (D) or glutamic acid (E) and a charge of 0 for all other amino acids in the peptide immunogen and wherein the anionic CpG oligonucleotide has a net negative charge at a pH in the range of 5.0-8.0 and is a single-stranded DNA comprising 8 to 64 nucleotide bases with a repeat of a cytosine-guanidine motif and the number of repeats of the CpG motif is in the range of 1 to 10.

The Examiner cites the following documents as evidence of unpatentability:

Ladd et al.	WO 94/25060	Nov. 10, 1994
Krieg et al.	WO 01/22972 A2	Apr. 5, 2001

"Result no. 1 of the rng and result no. 1 of the rag search summary pages, cited by the Office, 02/17/2005." (Ans. 3.)

The Examiner rejected the claims as follows:

(1) Claims 1, 5, 7-9, 12, 13, 18, and 19, as unpatentable under 35 U.S.C. § 103(a) over Krieg and Ladd, "as evidenced by result no. 1 of the rng and result no. 1 of the rag search summary pages" (Ans. 4);

(2) Claims 1, 4, and 6, as unpatentable under 35 U.S.C. § 103(a) over Krieg and Ladd (Ans. 8-9).

OBVIOUSNESS

ISSUE

The Examiner initially finds that SEQ ID NO: 1 of the instant application provides the nucleotide sequence of an oligonucleotide that meets the requirements of the oligonucleotide recited in claim 1 (Ans. 5-6). The Examiner also finds that SEQ ID NO: 9 of the instant application provides the amino acid sequence of a cationic peptide immunogen that meets the requirements of the peptide recited in claim 1 (*id.* at 6).

The Examiner cites Krieg as disclosing "a composition comprising an immunostimulatory nucleic acid and an anti-cancer therapy" (*id.*). The Examiner finds that one of the immunostimulatory nucleic acids taught by Krieg "is an anionic CpG oligonucleotide . . . [that] has the sequence set forth in SEQ ID NO: 429" which is "100% identical to the SEQ ID NO: 1 set forth in the claims" as evidenced by sequence search results (*id.*).

The Examiner further finds that Krieg discloses its compositions as including additional immunotherapeutic agents, but concedes that it is not apparent if Krieg's additional immunotherapeutic agents are "cationic peptide immunogens comprising a CLT epitope and a T helper cell epitope" as required by claim 1 (*id.* at 7). The Examiner cites Ladd as teaching a peptide that has the features required by claim 1 (*id.*).

The Examiner finds that Ladd's peptide immunogen is useful for treating, among other things, androgen-dependent carcinoma, prostatic carcinoma, and testicular carcinoma in males, and estrogen-dependent breast cancer in females (*id.*). The Examiner further finds that Ladd "refers to this cationic peptide immunogen as SEQ ID NO: 35 . . . [which] is 100%

identical to SEQ ID NO: 9 set forth in the claim" as evidenced by sequence search results (*id.*).

Based on the references' teachings, the Examiner finds that a person of ordinary skill in the art would have been prompted to combine the therapeutic agents of Krieg and Ladd to treat "androgen-dependent carcinoma, prostatic carcinoma and testicular carcinoma in males; . . . and [to] prevent[] or treat[] estrogen-dependent breast cancer in females" (*id.* at 7-8).

Appellant contends that the Examiner failed to make a prima facie case of obviousness (App. Br. 5-6).[2] Specifically, Appellant urges that Krieg does not disclose or suggest that its immunostimulatory oligonucleotides have, or should have, negative charges (*id.* at 8). Rather, Appellant urges, the Examiner's finding that Krieg's oligonucleotides inherently have a negative charge is not based on the prior art, but instead improperly based on Appellant's own Specification (Reply Br. 6-7).

Moreover, Appellant argues, although Krieg discloses combining its oligonucleotides with anti-cancer therapeutic agents, Krieg does not disclose that those agents are peptide immunogens, nor does Krieg discuss "complexing the immunostimulatory ODN [(oligodeoxynucleotide)] with the anti-cancer agent" (App. Br. 8; *see also* Reply Br. 5-6). Appellant also urges that, in view of Jones'[3] disclosure of the necessity of screening several hundred oligonucleotides for immunostimulatory properties, an ordinary

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[2] Appeal Brief entered March 19, 2008.
[3] Trevor R. Jones et al., *Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys*, 17 VACCINE 3065-3071 (1999).

artisan would not have expected to be able to "select the appropriate CpG oligonuclotide [sic] to be an effective adjuvant for particular peptide immunogens. In contrast, Applicant has provided a way to select effective CpG ODNs that [are] effective when combine[d] with a cationic peptide immunogen[]" (Reply Br. 4).

Appellant further argues that, while Ladd teaches using LHRH (luteinizing hormone releasing hormone) peptides conjugated to a T helper cell epitope for treating prostate cancer, Ladd does not teach or suggest "complexing the LHRH-T helper cell epitope combination with anionic CpG oligonucleotides" (App. Br. 10). Appellant also urges that the Examiner's finding that Ladd's peptides inherently have a positive charge is not based on the prior art, but instead improperly based on Appellant's own Specification (Reply Br. 8).

Thus, Appellant argues, "[o]nly when one recognizes that specific CpG ODNs are negatively charged due to the presence of a phosphodiester, such as a phosphorothiorate moiety, would one be motivated to identify, select, or form cationic peptide immunogens" (*id.*). Therefore, Appellant concludes:

> The formation of a stable immunogen complex using the selected or modified CpG oligonucleotide with a selected or modified peptide with a positive charge is not found in the cited prior references Krieg et al or Ladd et al. How to select or obtain an anionic CpG oligonucleotide and a cationic peptide to form a stable immunogen complex is found in Applicant's disclosure.

(App. Br. 13.)

Appellant also contends that "it is surprising that by forming microparticles of the stabilized immunogen complex, a higher titer of

antibodies is obtained. See results shown in Figs 7 and 9. Moreover, the virus neutralization activity of the antibodies elicited is improved" (*id.*).

Appellant does not argue the claims subject to this ground of rejection separately. We select claim 1 as representative of the rejected subject matter. *See* 37 C.F.R. § 41.37(c)(1)(vii).

In view of the positions advanced by Appellant and the Examiner, the issues with respect to this rejection are (a) whether Appellant has shown that the Examiner erred in concluding that an ordinary artisan would have considered the complex recited in claim 1 prima facie obvious in view of the teachings of Krieg and Ladd, and (b) if the Examiner did not err with respect to prima facie obviousness, whether Appellant has shown that the Examiner erred in finding that Appellant did not present sufficient evidence of unexpected results to overcome the prima facie case.

FINDINGS OF FACT ("FF")

1. Claim 1 recites a stabilized immunostimulatory microparticulate complex that has two components: (1) a cationic peptide immunogen, and (2) an anionic CpG oligonucleotide.

2. The cationic peptide immunogen component of claim 1's complex must have either a target B cell antigen, or a CTL epitope and a T helper cell epitope, and must also have a net positive charge at a pH in the range of 5.0 to 8.0. The positive charge is calculated by assigning a +1 charge for each lysine (K), arginine (R) or histidine (H), a -1 charge for each aspartic acid (D) or glutamic acid (E) and a charge of 0 for all other amino acids.

3. Claim 19 depends ultimately from claim 1, and specifies that "the cationic immunogen is selected from the group consisting of SEQ ID NO: 7, 8 and 9 and a mixture thereof."

4. The anionic CpG oligonucleotide component of claim 1's complex must have a net negative charge at a pH in the range of 5.0-8.0, and be a single-stranded DNA comprising 8 to 64 nucleotide bases with a repeat of a cytosine-guanidine motif, with the number of repeats of the CpG motif being in the range of 1 to 10.

5. Claim 13 ultimately depends from claim 1, and specifies that the "CpG oligonucleotide is . . . SEQ ID NO: 1."

6. The Specification discloses that "'anionic molecules' as described herein refers to molecules, which are negatively charged at a pH in the range of 5.0-8.0. The net negative charge on the oligomer or polymer is calculated by assigning a -1 charge for each phosphodiester or phosphorothioate group in the oligomer" (Spec. [0037]).

Thus, "[m]ultiply charged anionic molecules, such as the short CpG oligomers possess a net negative charge when the pH is in the range 5.5-7.4 in aqueous solutions" (*id.* at [0080].)

7. The Specification discloses:

> The net negative charge on the polynucleotide or oligonucleotide is calculated by assigning a -1 charge for each phosphodiester or phosphorothioate group in the oligomer. A suitable anionic oligonucleotide is a single- stranded DNA molecule with 8 to 64 nucleotide bases, with a repeated CpG motif and the number of repeats of the CpG motif is in the range of 1 to 10. . . .
>
> Most preferably, the CpG oligonucleotide is selected from a group consisting of . . . SEQ ID NO: 1, [which is] a 32 base length oligomer, and . . . SEQ ID NO: 2, [which is] a 24 base length oligomer plus an phosphorothioate bridging group . . . .

(*Id.* at [0065]-[0067].)

8. The Specification discloses that the claimed complex is prepared simply by mixing the negatively charged oligonucleotide and the positively charged peptide immunogen in an aqueous solution:

> The immunostimulatory complex of the present invention is prepared by a controlled self-assembling process wherein the anionic CpG oligonucleotide in aqueous solution is added to an aqueous solution of the cationic peptide immunogen. Suitable aqueous solutions for the preparation of an immunostimulatory complex is selected from the group consisting of distilled deionized water (DDW), normal saline (NS) or phosphate buffered saline (PBS).

(*Id.* at [0079].)

9. Krieg discloses "immunostimulatory nucleic acid compositions [that] . . . contain poly T sequences and/or have greater than 25 % T nucleotide residues. . . . These immunostimulatory nucleic acids function in a similar manner to nucleic acids containing CpG motifs. The invention also encompasses preferred CpG nucleic acids" (Krieg, abstract).

10. Claim 101 of Krieg recites "[a] composition comprising an immunostimulatory nucleic acid selected from the group consisting of . . . SEQ ID NO: 426-947 . . ., and a pharmaceutically acceptable carrier" (*id.* at 166).

11. It is undisputed that Krieg's SEQ ID NO: 429, which encodes one of Krieg's immunostimulatory nucleic acids, is identical to Appellant's SEQ ID NO: 1.

12. Krieg discloses that "the immunostimulatory nucleic acids are useful as vaccine adjuvants" (Krieg 84).

13. Krieg discloses that the "immunostimulatory nucleic acids may also be administered in conjunction with an anti-cancer therapy" (*id.* at 100).

14. Krieg characterizes the anti-cancer utility of its immunostimulatory nucleic acids as follows:

> [T]he Py-rich and TG nucleic acids are useful for treating cancer. The Py-rich and TG nucleic acids are also useful according to other aspects of the inven[t]ion in preventing cancer (e.g., reducing a risk of developing cancer) in a su[b]ject at risk of developing a cancer. The cancer may be selected from the group consisting of . . . breast cancer, . . . prostate cancer, . . . and testicular cancer.
>
> Py-rich and TG nucleic acids may also be used for increasing the responsiveness of a cancer cell to a cancer therapy (e.g., an anti-cancer therapy), optionally when the Py-rich or TG immunostimulatory nucleic acid is administered in conjunction with an anti-cancer therapy. The anti-cancer therapy may be a chemotherapy, a vaccine (e.g., an in vitro primed dendritic cell vaccine or a cancer antigen vaccine) or an antibody based therapy.

(*Id.* at 14.)

15. Thus, in one embodiment, Krieg discloses "a composition, comprising an immunostimulatory nucleic acid and an anti-cancer therapy, formulated in a pharmaceutically-acceptable carrier and in an effective amount to treat a cancer or to reduce the risk of developing a cancer" (*id.* at 18).

16. Ladd discloses "immunogenic luteinizing hormone releasing hormone (LHRH) peptides that lead to functional suppression of LHRH levels in males or females" (Ladd 1).

17. Ladd discloses that its immunogenic synthetic peptides have "about 30 to about 90 amino acids [and] contain[s] an immunostimulatory invasin domain, a helper T cell (Th) epitope and a peptide hapten" (*id.* at 6).

The hapten moiety of Ladd's peptides can include "any . . . B cell epitope (such as from pathogenic organisms) or a CTL (cytotoxic T cell)-generating epitope" (*id.* at 7).

18. Ladd discloses:

> [P]eptides of this invention are Peptide A (SEQ ID NO:10; Table 1), Peptides F-L (SEQ ID NOS:11-17; Table 4) and Peptides 18-41 (SEQ ID NOS:18-41; Table 5). Preferred peptides include Peptide A, Peptide F and Peptide H. More preferred peptides include peptides 18, 19, 32-35, H and K, and most preferably 19, 32, H and K.

(*Id.* at 27.)

19. SEQ ID NO: 33 of Ladd (*see id.* at 115) is identical to SEQ ID NO: 9 of the instant application, and recited in claim 19 of the instant application.[4]

20. Ladd discloses:

> Another aspect of this invention provides a vaccine composition comprising an immunologically-effective amount of one or more of the peptides of this invention and a pharmaceutically acceptable carrier. Such vaccine compositions are used in the methods of . . . treating prostatic hyperplasia, androgen-dependent carcinoma, prostatic carcinoma, testicular carcinoma, . . . or prevention or treatment of estrogen-dependent breast tumors.
>
> Accordingly, the subject peptides can be formulated as a vaccine composition using adjuvants, pharmaceutically-acceptable carriers or other ingredients routinely provided in vaccine compositions. Such formulations are readily determined by one of ordinary skill in the art . . . .

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[4] While the Examiner finds that Appellant's SEQ ID NO: 9 is 100% identical to Ladd's SEQ ID NO: 35 (Ans. 7), and Appellant does not dispute that finding, comparison of Ladd's SEQ ID NO: 33 to Appellant's SEQ ID NO: 9 shows them to be identical (*see* Ladd 115; *see also* Sequence Listing 4 (entered April 23, 2002)).

(*Id.* at 29.)

21. Ladd discloses that "[v]accines which contain cocktails of two or more of the subject peptides enhance immunoefficacy in a broader population and thus provide a better immune response against LHRH" (*id.* at 30).

22. Jones discloses experiments in which CpG-containing oligonucleotides were co-administered with peptide antigens to *Aotus* monkeys (Jones 3065 (abstract)). Jones found that its data "indicate that oligodeoxynucleotides containing CpG motifs improve immunogenicity of peptide immunogens in non-human primates, and may be immunopotentiators useful in humans" (*id.*).

PRINCIPLES OF LAW

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court rejected a rigid approach to the question of obviousness, and ultimately reaffirmed that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976)).

The Court reasoned that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.*

The Court advised, however, that

> it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention*

> *does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added).

The Court also cautioned that, "[i]n determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103." *Id.* at 419.

Nonetheless, a prima facie case of obvious cannot be based on a fact not disclosed in the prior art. *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) ("'That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.' Such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.") (quoting *In re Spormann*, 363 F.2d 444, 448 (CCPA 1966)).

On the other hand, the inherent properties of prior art elements need not be disclosed in the prior art. *See In re Woodruff*, 919 F.2d 1575, 1577-78 (Fed. Cir. 1990) (obviousness rejection affirmed where using claimed elements in the manner suggested by the prior art necessarily resulted in claim-recited effect); *see also MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("Inherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.").

ANALYSIS

Appellant's arguments do not persuade us that the Examiner erred in concluding that an ordinary artisan would have considered the complex recited in claim 1 prima facie obvious in view of the teachings of Krieg and Ladd. Claim 1 recites a stabilized immunostimulatory microparticulate complex that has two components: (1) a cationic peptide immunogen, and (2) an anionic CpG oligonucleotide.

Ladd discloses that a peptide encompassed by claim 1 is desirable in an anti-cancer cancer vaccine composition used for treating prostatic carcinoma, testicular carcinoma, and estrogen-dependent breast tumors (FF 20). Ladd discloses that adjuvants are suitable in those compositions (*id.*).

Ladd does not appear to include an oligonucleotide having the properties recited in claim 1 in its compositions.

However, Krieg discloses that an oligonucleotide having those properties is useful as an adjuvant in vaccine compositions (FF 12), is useful in treating breast, prostate, and testicular cancers, and is useful in combination with other cancer therapies, including anti-cancer vaccines (FF 14). In view of these disclosures, we agree with the Examiner that an ordinary artisan would have been prompted to combine Krieg's oligonucleotide with Ladd's peptide into a single vaccine composition useful for treating breast, prostate, and testicular cancers.

Thus, rather than being based on a hindsight reconstruction of Appellant's disclosure, or on any unknown inherent properties of the two agents, the impetus for combining the agents would have been based solely on the prior art.

It may be true, as Appellant argues, that neither of the references states that either of the two agents should be complexed with other agents. However, the two claimed agents self-assemble into a complexed form when simply combined in aqueous solutions suitable for administration to patients (*see* FF 8). Thus, we agree with the Examiner that following the teachings of the prior art would have resulted in a composition having a complexed form encompassed by claim 1.

Appellant argues that the Examiner has not shown that Ladd's peptides and Krieg's oligonucleotides have the positive and negative charges required by claim 1. Appellants' argument is not supported by the evidence of record, however.

As noted above, and pointed out by the Examiner, Ladd discloses that one of its cancer-treating peptides has the same sequence as one of the peptides recited in Appellant's claim 19, and is a peptide disclosed by Appellant as having the properties recited for the peptides in claim 1 (*see* FF 19). As also noted above, and also pointed out by the Examiner, Krieg discloses that one of its cancer-treating oligonucleotides has the same sequence as the oligonucleotide recited in Appellant's claim 13 (*see* FF 11), and is an oligonucleotide disclosed by Appellant as one of the two most preferred oligonucleotides having the properties recited in claim 1 (*see* FF 7).

Because Ladd's peptide has a structure that is identical to the structure of a peptide disclosed and claimed by Appellant as having the properties recited in claim 1, Ladd's peptide must therefore also have the properties recited in claim 1, including the required positive charge. Similarly, by virtue of its identical structure, Krieg's oligonucleotide must have the same

properties as the oligonucleotide recited in claim 1, including the negative charge.

We are therefore not persuaded that the Examiner erred in finding that combining Ladd's peptide and Krieg's oligonucleotide, as suggested by the prior art, would result in a complex encompassed by claim 1. While it might be true that Appellant's purpose for combining the agents, producing a stable complex, is different than the reason suggested by the references, that fact does not undermine the Examiner's prima facie case. *See KSR*, 550 U.S. at 419 ("In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.").

We are also not persuaded that Jones' disclosure shows error in the Examiner's conclusion of obvious. While it might be true that a significant amount of experimentation was required, Jones' ultimate conclusion was that "oligodeoxynucleotides containing CpG motifs improve immunogenicity of peptide immunogens in non-human primates, and may be immunopotentiators useful in humans" (FF 22). Jones therefore bolsters rather than weakens the Examiner's prima facie case, given Krieg's explicit disclosure that such oligonucleotides were useful in therapeutic treatments.

Appellant suggests that the claimed complex has unexpected properties, as shown by a higher antibody titer, and by the elicited antibodies' virus neutralization activity (App. Br. 13). However, Appellant has not explained in any detail the significance of any data presented.

Moreover, "any superior property must be *unexpected* to be considered as evidence of non-obviousness." *Pfizer, Inc. v. Apotex, Inc.,*

480 F.3d 1348, 1371 (Fed. Cir. 2007). Thus, "[m]ere improvement in properties does not always suffice to show unexpected results. . . . [W]hen an applicant demonstrates *substantially* improved results . . . and *states* that the results were *unexpected*, this should suffice to establish unexpected results *in the absence of* evidence to the contrary." *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995).

Krieg explicitly discloses that its oligonucleotides act as adjuvants, and can improve the efficacy of anti-cancer therapies, including vaccines (FF 12, 14). In view of this disclosure, combined with the lack of any clear explanation as to why any improvement shown in the Specification might be unexpected in light of Krieg's disclosure, we are not persuaded that Appellant has presented sufficient evidence to overcome the Examiner's prima facie case.

In sum, we are not persuaded that the Examiner failed to make a prima facie case of obviousness with respect to claim 1, nor are we persuaded that Appellant has adequately advanced sufficient evidence of secondary considerations to overcome the Examiner's prima facie case. We therefore affirm the Examiner's rejection of claim 1 as obvious over Krieg and Ladd.

Because they were not argued separately, claims 5, 7-9, 12, 13, 18, and 19 fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner separately rejected claims 1, 4, and 6 as being obvious over Krieg and Ladd (Ans. 8-9). The Examiner relied on Ladd to show that an ordinary artisan would have considered it obvious to provide a mixture of peptides, as recited in claim 4, and that a mixture of Ladd's peptides would have the positive charge recited in claim 6 (*id.*; *see also* FF 21).

Appellants rely on their previous arguments in traversing this rejection (*see* App. Br. 13-14). As discussed above, Appellant's arguments do not persuade us that the Examiner erred in concluding that claim 1 would have been obvious to an ordinary artisan in view of Krieg and Ladd. As we detect no other deficiency in the Examiner's prima facie case with respect to claims 4 and 6, we affirm the Examiner's rejection of those claims as well.

SUMMARY

We affirm the Examiner's obviousness rejections of claims 1, 4-9, 12, 13, 18, and 19 over Krieg and Ladd.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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